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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6569]

Clinical Decision Support Software; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Clinical Decision Support Software." This final guidance provides clarity on FDA's oversight of clinical decision support (CDS) software intended for health care professionals with the purpose of describing FDA's regulatory approach to CDS software functions. This guidance clarifies the types of CDS functions that do not meet the definition of a device as amended by the 21st Century Cures Act (Cures Act).

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or

confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. [FDA-2017-D-6569] for "Clinical Decision Support Software; Guidance for Industry and Food and Drug Administration Staff." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy,

including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Clinical Decision Support Software; Guidance for Industry and Food and Drug Administration Staff" to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Brendan O'Leary, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5530, Silver Spring, MD 20993-0002, 301-796-6898; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911 or Kristina Lauritsen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6162, Silver Spring, MD 20993-0002, 301-796-8936.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has long regulated software that meets the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(h)), including software that is intended to provide decision support to health care professionals, patients, or caregivers for the diagnosis, treatment, prevention, cure, or mitigation of diseases or other conditions (often referred to as CDS software). Section 3060(a) of the Cures Act, enacted on December 13, 2016 (Pub. L. 114-255), amended section 520 of the FD&C Act (21 U.S.C. 360j) to exclude certain medical software functions, including certain decision support software, from the definition of device under section 201(h) of the FD&C Act.

This guidance describes CDS software functions that do not meet the definition of a device in the context of and based on the criteria from section 520(o) of the FD&C Act. This guidance also further clarifies that FDA's existing digital health policies continue to apply to software functions that meet the definition of a device, including those that are intended for use by patients or caregivers. For example, some decision support software functions may be identified in other guidance documents as software functions for which, based on our current understanding of the risks of these software functions, FDA does not intend at this time to enforce compliance with applicable device requirements of the FD&C Act, including, but not limited to, premarket clearance and approval requirements.

A notice of availability of the draft guidance appeared in the *Federal Register* of September 27, 2019 (84 FR 51167). FDA considered comments received and revised the guidance as appropriate in response to the comments. In this final guidance, FDA provides clarification on the terminology of "Clinical Decision Support" and focuses solely on the criteria for Non-Device CDS. In response to comments received, the final guidance no longer contains complementary information from the International Medical Device Regulators Forum risk categories, and the guidance provides additional explanation for how a software function, regardless of its complexity, can be intended for the purpose of enabling a healthcare professional to independently review the basis for the software function's recommendations, such that the recommendations are not primarily relied upon by the healthcare professional.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Clinical Decision Support Software. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products. This guidance document is also available at https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, or https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs. Persons unable to download an electronic copy of "Clinical Decision Support Software; Guidance for Industry and Food and Drug Administration

Staff" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400062 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
807, subpart E	Premarket notification	0910-0120
814, subparts A through E	Premarket approval	0910-0231
814, subpart H	Humanitarian Device Exemption	0910-0332
812	Investigational Device Exemption	0910-0078
"De Novo Classification Process (Evaluation of Automatic Class III Designation)"	De Novo classification process	0910-0844
800, 801, and 809	Medical Device Labeling Regulations	0910-0485
314	Applications for FDA Approval to Market a New Drug	0910-0001
601; Form FDA 356h	Biologics License; Application to Market a New Drug or Abbreviated New Drug or Biologic for Human Use--Form FDA 356h	0910-0338

Dated: September 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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